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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/523,853      | 02/07/2005  | Hideko Kosaka        | 10921.0279USWO      | 4428             |

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EXAMINER

RAMILLANO, LORE JANET

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1743

DATE MAILED: 11/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/523,853

Applicant(s)

KOSAKA, HIDEKO

Examiner

Lore Ramillano

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2006.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 19-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 19-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date 11/3/06
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. In applicant's reply filed on 8/3/06, applicant amended claim 1, cancelled claims 2-18, and added new claims 19-22.

### Response to Amendment

2. The rejections over the prior art are withdrawn. A new rejection follows.

### Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claim 1** is rejected under 35 U.S.C. 102(b) as being anticipated by Profitt et al. ("Profitt," US 60/360880).

Profitt discloses a test piece for protein assay comprising a single acidic indicator, tetrabromophenol blue (p. 13, lines 3-30); and a cationic surfactant (p. 18, lines 23-30).

5. **Claim 19** is rejected under 35 U.S.C. 102(b) as being anticipated by Omoto et al. ("Omoto," US 5183742).

Omoto discloses a test piece for protein assay comprising a nonionic surfactant, polyethylene glycol (column 9, lines 19-26); and an acidic indicator, tetrabromophenol blue (column 9, lines 40-48).

**Claim Rejections - 35 USC § 103**

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. **Claims 20-22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Profitt in view of Omoto and Kosaka (US 5955027).

Profitt discloses a test piece for protein assay comprising a single acidic indicator, tetrabromophenol blue (p. 13, lines 3-30); and a cationic surfactant (p. 18, lines 23-30).

While Profitt discloses a test piece comprising of different surfactants, Profitt does not specifically disclose utilizing a combination of the following: polyethylene glycol, benzyltrimethylammonium bromide, and zephiramine.

Omoto discloses a test piece for protein assay comprising anionic, cationic, and nonionic surfactants, such as polyethylene glycol (column 9, lines 19-26); and an acidic indicator, tetrabromophenol blue (column 9, lines 40-48).

Kosaka discloses a reagent composition for detecting an analyte in a liquid sample. The reagent composition comprises a surfactant or two or more surfactants used in combination. The surfactants comprise of any anionic, cationic, nonionic, and amphoteric surfactants. (column 2, line 66 to column 4, lines 52).

Profitt, Omoto, and Kosaka are analogous art because they are from the same field of endeavor, test devices and compositions that can detect a variety of components in body fluids. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Profitt with the surfactant limitations of Omoto and Kosaka, as stated above, because surfactants improve the reactivity and the sensitivity between the reagent or indicator component and the analyte of interest (Kosaka, column 4, lines 43-52).

**Response to Arguments**

10. Applicant's arguments with respect to claims 1, 19, and 20 have been considered but are moot in view of the new ground(s) of rejection.

**Conclusion**

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lore Ramillano whose telephone number is (571) 272-7420. The examiner can normally be reached on Mon. to Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax


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phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lore Ramillano  
Examiner  
Art Unit 1743

10/20/06

  
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